

REMARKS

The withdrawal of the final status of the rejection and of one of the grounds of rejection is appreciated.

The rejection of claim 55 (sic. claim 53) as being indefinite has been overcome.

The rejection of claim 53 has been overcome by amendment by deleting the requirement for a determination that the blood withdrawal is insufficient. The deletion moots the issue of whether the determination of insufficient withdrawal of blood is indefinite. Further, a determination that the withdrawal of blood is insufficient is unnecessary to the patentability of the claim 53. However, the requirement for a determination of insufficient blood flow rate has been added to dependent claim 55. The determination is definite in claim 55 because it is quantified the claim to be a blood flow rate through the needle less than 40 milliliter per minute.

The rejection (claims 53 to 59) for obviousness based on Truitt et al (U.S. Patent No. 5,910,252) in view of Glantz (U.S. Patent No. 5,5,749,835) is traversed. There is no evidence of a suggestion to combine Truitt et al and Glantz to form the claimed invention.

The claimed invention is neither simply finding an optimal length of a catheter nor the recognition of another advantage of the catheters disclosed in Truitt and Glantz. Truitt discloses a central access catheter and not a peripheral access catheter. Glantz teaches locating a catheter tip in a heart. In contrast, the invention is directed to a method to withdraw blood from a peripheral catheter having an extended length to reach a large or great vein or the vena cava the and withdrawal of blood by applying suction to the catheter (claim 52) and to a method in which an attempt to withdraw blood is first made by a withdrawal needle in a peripheral vein and thereafter blood is withdrawn by inserting an extended catheter into a peripheral vein to access a reservoir of blood in the large or great vein or vena cava. These claimed methods are not

properly characterized as optimizing a length of a catheter and would not flow naturally from the teachings of Truitt and Glantz. Accordingly, the Response to Arguments in the USPTO Action does not provide a credible rebuttal to arguments for patentability set forth by application.

The claimed invention addresses a problem that arises in ultrafiltration when blood withdrawal through a peripheral vein is insufficient to provide the blood flow, e.g., less than 40 ml/min, for the intended treatment. The invention solves this problem by substituting a mid-length catheter, e.g., PICC line, for a short catheter needle. The mid-length catheter is introduced into a peripheral vein and extends through the venous system to a large vein or other reservoir of blood in the patient.

The claimed invention would not have been obvious in view of the blood treatment device shown in Truitt and the method to locate a catheter shown in Glantz. These references do not recognize the problem addressed by the inventor or suggest a solution to that problem. Glantz and Truitt provide no suggestion to form the claimed invention and would not render the invention to have been obvious.

Truitt does not suggest or teach peripheral vein access. Truitt discloses a blood treatment system that appears to access a central vein. *See* Truitt Fig. 1 (lines 33, 34 attach to torso of patient). Central vein access has traditionally been used to provide the large volume of blood used for ultrafiltration, hemofiltration and hemodialysis blood treatments. *See e.g.*, 6,685,664 (Background of the Invention). Central venous access lines tend to be much too large for peripheral vein access. It would be counter to such traditional blood treatment systems to rely on a narrow peripheral blood catheter to withdraw blood. It would have been counter-intuitive to use a narrow peripheral catheter tube to access a central vein. Truitt does not teach a method in which blood is first withdrawn from a surface peripheral vein, or a method in which a

determination is made that the amount of blood through the surface needle is inadequate and thereafter a catheter is inserted into a peripheral vein of the patient to "one of a large vein, great vein or vena cava to access a reservoir of blood for continuous blood withdrawal."

Glantz discloses a method for locating a tip of a catheter in the heart of a patient. Glantz does not teach peripheral vein insertion of a catheter to withdraw blood, or a method that includes a determination that a peripheral vein needle is insufficient for blood withdrawal and thereafter the insertion of a catheter to withdraw blood. There is no suggestion in Glantz to use a PICC catheter to withdraw blood into the Truitt blood treatment system. Glantz does not suggest that a narrow peripheral catheter is suitable for blood withdrawal in an ultrafiltration system, that a PICC catheter may be used to access large vein to avoid vein collapse or that a PICC catheter should be inserted after determining that a surface peripheral needle provides inadequate blood flow. There is no suggestion or motivation evident from the prior art to use a PICC catheter to withdraw blood from a central vein as a substitute for a peripheral catheter that accesses just a peripheral vein.

Secondary Consideration: Invention Recognized by Other As An Advancement In the Art

It is appreciated that Jaski et al is no longer being treated as a prior art reference. However, the USPTO has not set forth in writing a response to Applicant's argument that Jaski et al is a recognition of the invention in a peer reviewed article. As such, Jaski et al is a secondary consideration of non-obviousness. Jaski et al describes the same ultrafiltration system that is the subject of this application, and is evidence of non-obviousness. The

ultrafiltration system described in this application, i.e., made by CHF Solutions, is the subject of the Jaski et al article.¹ [Jaski Article, p. 228.]

Jaski et al describes the use of a mid-length catheter ("25 or 35 cm") with the ultrafiltration system and, thus, is directly relevant to the subject matter claimed in this application. Jaski Article, p. 228. Jaski et al state that: "[t]o our knowledge, this is the first clinical report of rapid removal of extracellular and intravascular fluid volume excess via ultrafiltration without use of a central venous catheter," ("Discussion" heading at page 229); "[r]apid removal of extracellular and intravascular fluid volume excess can be safely achieved via peripherally inserted ultrafiltration without the need for central venous catheter placement" ("Conclusions" heading of the Abstract at page 227); and "[u]se of conventional systems, however, may be cumbersome, requiring physician placement of double-lumen central venous catheter ..." ("Background" heading of the Abstract at page 227). Accordingly, Jaski et al teach that central venous catheters are conventional for ultrafiltration; peripheral vein access for ultrafiltration was a relatively Previously Presented technique as of 2003, and that peripheral vein access with a mid-length catheter successfully treated patients suffering from circulatory volume overload.

Jaski et al is secondary evidence of non-obvious because it shows that "conventional systems" where cumbersome and favorably discusses ultrafiltration using peripheral vein access. Jaski et al is an article published by the Journal of Cardiac Failure and is a peer-reviewed article. The statements in the article regarding the benefits of peripheral access for ultrafiltration and the difficulties with the prior art central access support a finding that the claimed invention was not obvious.

¹ Jaski et al was prepared with the technical and financial support of the owner of this application.

Double Patenting Rejection Overcome by Terminal Disclaimer:

A terminal disclaimer is being submitted herewith to overcome the obviousness double patenting rejection.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Jeffry Nelson/

Jeffry H. Nelson
Reg. No. 30,481

JHN:glf
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100